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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,052	09/08/2008	Kambiz Shekdar	002298-0003-101	5470
81098	7590	05/05/2011	EXAMINER	
Ropes & Gray LLP			STEELE, AMBER D	
Patent Docketing 39/361				
1211 Avenue of the Americas			ART UNIT	
New York, NY 10036-8704			PAPER NUMBER	
			1654	
			NOTIFICATION DATE	
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			05/05/2011	
			ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPatentMail@ropesgray.com
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Office Action Summary	Application No.	Applicant(s)	
	10/589,052	SHEKDAR ET AL.	
	Examiner	Art Unit	
	Amber D. Steele	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19,21,25,34,46,49,50,103,109,110,114 and 117-144 is/are pending in the application.
- 4a) Of the above claim(s) 46, 49, 50, 103, 109, 110, 114, 128, and 131-144 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19,21,25,34,117-127,129 and 130 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :3/28/11, 6/9/10, 3/16/10, 2/17/10, 2/2/10, 10/9/09, 9/17/09, 7/29/09, 5/6/09, 11/10/08, 6/13/08, 9/6/07, 8/2/07, and 5/6/09.

DETAILED ACTION

Status of the Claims

1. Claims 1-116 were originally filed.

The preliminary amendment to the claims received on August 10, 2006 canceled claims 2-18, 20, 22-24, 26-33, 35-37, 39-40, 43, 45, 47-48, 51-102, 104-108, 111-113, and 115 and amended claims 21, 25, 46, 109, and 114.

The amendment to the claims received on March 28, 2011 canceled claims 1, 38, 41, 42, 44, and 116; amended claims 19, 21, 25, 34, 46, 49, 50, 103, 109, 110, and 114; and added new claims 117-144.

Claims 19, 21, 25, 34, 46, 49, 50, 103, 109, 110, 114, and 177-144 are currently pending.

Claims 19, 21, 25, 34, 117-127, 129, and 130 are currently under consideration.

Election/Restrictions

2. Applicant's election of Group II in the reply filed on March 28, 2011 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Upon further consideration, the restriction between Groups I, II, and III is withdrawn (i.e. all methods of isolating cell/cells are considered a single invention). In addition, it is respectfully noted that any attempts by applicant or applicants' representative to alter the final outcome of the elected method (i.e. isolation of cell or cells), present new claims with different method steps, etc. may result in a restriction requirement or withdrawal of claims via election by original presentation.

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3. Claims 46, 49, 103, 109, 110, 133-144 (i.e. drawn to nonelected Group IX); 50 (i.e. drawn to nonelected Group VIII); and 114, 128, 131, and 132 (i.e. drawn to nonelected Groups IV, V, or X) are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 28, 2011. In addition, it is noted that claim 114 is an improper use claim. Applicants are respectfully directed to MPEP § 2173.05(q).

Priority

4. The present application claims status as a 371 (National Stage) of PCT/US05/05080 filed February 17, 2005 which claims the benefit of 60/546,075 filed February 18, 2004.

5. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/546,075, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. U.S. provisional application 60/546,075 fails to disclose shRNA. Therefore, any claims referring to shRNA have a priority date of February 17, 2005.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on 3/28/11, 6/9/10, 3/16/10, 2/17/10, 2/2/10, 10/9/09, 9/17/09, 7/29/09, 5/6/09, 11/10/08, 9/6/07, 8/2/07, and 5/6/09 are being considered by the examiner. Please note: if only abstracts or Table of Contents were provided then only the abstract or Table of Contents was considered.
7. The information disclosure statement (IDS) submitted on 6/13/08 is being considered by the examiner, in part. Translations for the Japanese Patent Application Abstracts were not provided, therefore, the abstracts were not considered.

Abstract

8. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

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9. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as “means” and “said,” should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, “The disclosure concerns,” “The disclosure defined by this invention,” “The disclosure describes,” etc.

10. This application does not contain an abstract of the disclosure as required by 37

CFR 1.72(b). An abstract on a separate sheet is required.

Specification

11. The disclosure is objected to because of the following informalities: the first line of the specification does not contain the PCT information. Since the PCT is part of a priority chain, the first line of the specification should refer to the PCT.

Appropriate correction is required.

12. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See pages 39-41, 47, and 60.

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13. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 120 and 127 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 120 and 127 recite the limitations "the proteins encoded" in respective lines 2-3 and 1-2. There is insufficient antecedent basis for this limitation in the claim.

16. Claim 121 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. One of skill in the art would not be able to determine the scope of the presently claimed invention. For example, claim 121 is dependent on claim 19 and thus incorporates all of the method steps of present claim 19. However, it appears that the method steps recited in present claim 121 are replacing the method steps recited in present claim 19. Applicants may wish to utilize "further comprising" language (i.e. either further comprising all method steps or only those methods steps referring to the second RNA expression library). However, no new matter may be added. Alternatively, claim 121 may be written as an independent claim.

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17. Claim 125 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. One of skill in the art would not be able to determine the scope of the presently claimed invention. Present claim 125 is considered an improper use claim. Therefore, it is not clear what method steps are required by the claim. See MPEP § 2173.05(q).

18. Claim 127 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. One of skill in the art would not be able to determine the scope of the presently claimed invention. How can a cell be isolated when the RNA or protein is lethal? The breadth of present claim 126 can not be relied on to overcome the present rejection.

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

20. Claims 19, 21, 25, 34, 117-127, 129, and 130 are rejected under 35 U.S.C. 102(a) as being anticipated by Shekdar et al. U.S. Patent 6,692,965 issued February 17, 2004 (filed November 22, 2000; effective filing date November 23, 1999).

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For present claims 19, 21, 25, 34, 117-127, 129, and 130, Shekdar et al. teach methods comprising introducing into cells at least one DNA encoding at least one antisense RNA or mRNA (i.e. protein encoding; expression) and at least one epitope tag (i.e. encompassing library, first and second library, etc.), exposing the cells to molecular beacons that hybridize to the antisense RNA, mRNA, and/or nucleic acid encoding the epitope tag(s), isolating cells that fluoresce, and culturing cells to produce cell lines wherein cells can be pooled or mixed wherein the epitope tag can be in frame or out of frame with the DNA encoding the RNA, selection markers can be utilized, promoters are utilized, and the RNA or protein encoded by the RNA can be lethal to the cells (please refer to the entire specification particularly the abstract; columns 1-9, 11, 13-17; Examples; claims). Regarding the functional limitations (i.e. “preselected”, “test”, “same or related biological pathway”, “upstream or downstream of each other”, “modulating, activating, or repressing function to each other”, “dependent on each other for function or activity”, “components of the same complex”, or “same protein family”), applicants are respectfully directed to MPEP § 2173.05(g).

Therefore, the teachings of Shekdar et al. anticipate the presently claimed invention.

21. Claims 19, 21, 25, 117-120, 122-127, 129, and 130 are rejected under 35 U.S.C. 102(e) as being anticipated by Short et al. U.S. Patent Application Publication 2003/0215798 published November 20, 2003 (filed June 16, 1997).

For present claims 19, 21, 25, 117-120, 122-127, 129, and 130, Short et al. teach methods of identifying and isolating clones comprising introducing expression libraries into cells and utilizing molecular beacons to detect cells wherein selection markers, promoters, etc. may be

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utilized (please refer to the entire specification particularly the abstract; paragraphs 50-61, 77, 78, 116, 121-199).

Therefore, the teachings of Short et al. anticipate the presently claimed invention.

Double Patenting

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. Claims 19, 21, 25, 34, 117-127, 129, and 130 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,692,965. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed invention and the invention as claimed in U.S. Patent 6,692,965 are drawn to methods of generating cells/cell lines via introducing into cells DNA encoding at least one RNA, exposing cells to at least one molecular beacon that hybridizes to the RNA, isolating cells that fluoresce, and growing cells wherein the RNA includes antisense RNA which may be lethal to the cell, utilizing additional epitope tags that can be in frame or out of frame with the DNA encoding the RNA, utilizing conditional promoters, and utilizing drug resistant markers(see claims 1-33).

24. Claims 19, 21, 25, 34, 117-127, 129, and 130 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-43 of copending Application No. 12/771,223. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed invention and the invention as claimed in 12/771,223 are drawn to methods of generating a cell line via transfecting cells with at least one DNA encoding RNA, exposing cells to molecular beacons that hybridize to RNA, isolating cells that fluoresce, and growing cells wherein drug resistant

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markers are utilized, antisense RNA is utilized, epitope tags are utilized that can be in frame or out of frame, etc. (see claims 1-43).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/
Primary Examiner, Art Unit 1654

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